STATE OF CALIFORNIA
DEPARTMENT OF INDUSTRIAL RELATIONS
DIVISION OF WORKERS' COMPENSATION

NOTICE OF MODIFICATION TO TEXT OF PROPOSED REGULATIONS

Subject Matter of Regulations – Medical Treatment Utilization Schedule

TITLE 8, CALIFORNIA CODE OF REGULATIONS
SECTIONS 9792.20 - 9792.23

NOTICE IS HEREBY GIVEN that the Acting Administrative Director of the Division of Workers' Compensation, pursuant to the authority vested in her by Labor Code sections 59, 133, 4603.5, and 5307.3, proposes to modify the text of the following proposed regulations contained in Article 5.5.2 of Chapter 4.5, Subchapter 1, Division 1, of Title 8, California Code of Regulations:

Section 9792.20	Medical Treatment Utilization Schedule—Definitions
Section 9792.21	Medical Treatment Utilization Schedule
Section 9792.22	Presumption of Correctness, Burden of Proof and Strength of Evidence
Section 9792.23	Medical Evidence Evaluation Advisory Committee

PRESENTATION OF WRITTEN COMMENTS AND DEADLINE FOR SUBMISSION OF WRITTEN COMMENTS

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Members of the public are invited to present written comments regarding these proposed modifications. **Only comments directly concerning the proposed modifications to the text of the regulations will be considered and responded to in the Final Statement of Reasons.**

Written comments should be addressed to:

Maureen Gray, Regulations Coordinator
Department of Industrial Relations
Division of Workers' Compensation
Post Office Box 420603
San Francisco, CA 94142

The Division's contact person must receive all written comments concerning the proposed modifications to the regulations no later than **5:00 p.m. on April 16, 2006.** Written comments may be submitted by facsimile transmission (FAX), addressed to the contact person at (510) 286-0687. Written comments may also be sent electronically (via e-mail), using the following e-mail address: dwcrules@hq.dir.ca.gov.

AVAILABILITY OF TEXT OF REGULATIONS AND RULEMAKING FILE

Copies of the original text and modified text with modifications clearly indicated, and the entire rulemaking file, are currently available for public review during normal business hours of 8:00 a.m. to 5:00 p.m., Monday through Friday, excluding legal holidays, at the offices of the Division of Workers' Compensation. The Division is located at 1515 Clay Street, 17th Floor, Oakland, California.

Please contact the Division's regulations coordinator, Ms. Maureen Gray, at (510) 286-7100 to arrange to inspect the rulemaking file.

The specific modifications proposed include changes to the text of the proposed amendments Title 8, California Code of Regulations:

Section 9792.20	Medical Treatment Utilization Schedule—Definitions
Section 9792.21	Medical Treatment Utilization Schedule
Section 9792.22	Presumption of Correctness, Burden of Proof and Strength of Evidence
Section 9792.23	Medical Evidence Evaluation Advisory Committee

DOCUMENTS SUPPORTING THE RULEMAKING ADDED TO THE RULEMAKING FILE

- ACOEM Practice Guidelines, APG Insights, Fall 2006, *ACOEM's Revised Evidence-Based Occupational Medicine Practice Guidelines and Methodology*
- ACOEM Practice Guidelines, APG Insights, Winter 2005, *Acupuncture-Medical Literature Analysis and Recommendations*
- Amended Economic and Fiscal Impact Statement (Form 399)
- Amendments to ACOEM's Methodology Advances for Occupational Practice Guidelines, 2nd Edition, March 13, 2007
- *Cochrane Handbook for Systematic Reviews of Interventions 4.2.6*, September 2006, The Cochrane Collaboration, http://www.cochrane.org/resources/handbook/Handbook4.2.6Sep2006.pdf
- Comments from various interested parties concerning the regulations added to the rulemaking file
- *Evidence-based Medicine: How to Practice and Teach EBM* (2005), Third Edition, Straus, Richardson, Glasziou, Haynes, pp. 117-119, 281
- *Evidence Based Medicine: What it is and What it isn't*, http://www.bmj.com/cgi/content/full/312/7023/71
- *Evidence Report/Technology Assessment: Number 47, Systems to Rate the Strength of Scientific Evidence*, Agency for Healthcare Research and Quality (AHRQ), Summary, http://www.ahrq.gov/clinic/epcsums/strengthsum.htm
- Medical Board of California (MBC) website link, (http://www.medbd.ca.gov/alphalist.htm)
- MEDLINE, Information on MEDLINE from the Wikipedia Encyclopedia, as of the date of the March 2007 2nd 15-Day Notice, http://en.wikipedia.org/wiki/Medline
- SIGN 50: A guideline developers' handbook
  Methodology Checklist 2: *Randomised Controlled Trials*
  http://www.sign.ac.uk/guidelines/fulltext/50/checklist2.html
- State of Colorado, Division of Workers' Compensation, Executive Summary of the Medical Treatment Guideline Care Review and Cost Studies, http://www.coworkforce.com/dwc/PUBS/execsummary.pdf

- State of Colorado, Division of Workers' Compensation, Low Back Pain, Medical Treatment Guidelines, http://www.coworkforce.com/dwc/Rules/Rules2005/Final%20Exh.%201%20%20Low%20Back%20Pain.pdf

- State of Colorado, Division of Workers' Compensation, Medical Treatment Guidelines
    - Medical Treatment Guidelines Update Process
    - Evidence-Based Parameters
    - Consensus Parameters

- State of Colorado, Division of Workers' Compensation, Medical Treatment Guidelines, General Information, http://www.coworkforce.com/dwc/DivisionResources/mtgsummarybriefintro.pdf

- 2005 *California Workers' Compensation Losses and Expenses*, Workers' Compensation Insurance Rating Bureau (WCIRB), June 23, 2006, page 9

FORMAT OF PROPOSED MODIFICATIONS

Proposed Text Noticed for 45-Day Comment Period:

The new text is indicated by underlining, thus: underlined language.

Proposed Text Noticed for 1st 15-Day Comment Period on Modified Text:

Deletions from the regulatory text, as proposed in May 2006, are indicated by underline/single strike-through, thus: ~~deleted language.~~

Additions to the regulatory text, as proposed in May 2006, are indicated by double underline, thus: added language.

Proposed Text Noticed for 2nd 15-Day Comment Period on Modified Text:

Deletions from the regulatory text, as proposed in December 2006, are indicated by italics/double strike-through, thus: ~~*deleted language.*~~

Additions to the regulatory text, as proposed in December 2006, are indicated by italics/single underline, thus: *added language*.

SUMMARY OF PROPOSED CHANGES

Modifications to Section 9792.20 Medical Treatment Utilization Schedule—Definitions

Subdivision (b) setting forth the definition for the term "ACOEM Practice Guidelines" has been amended to set forth the correct source and address where a copy of the American College of Occupational and Environmental Medicine's Occupational Medicine Practice Guidelines, 2nd Edition (2004) may be obtained. A copy may be now obtained from the American College of Occupational and Environmental Medicine, 25 Northwest Point Blvd., Suite 700, Elk Grove

Village, Illinois, 60007-1030 (www.acoem.org). Amended proposed Section 9792.20(b) now states:

> "ACOEM Practice Guidelines" means the American College of Occupational and Environmental Medicine's Occupational Medicine Practice Guidelines, 2nd Edition (2004). The Administrative Director incorporates the ACOEM Practice Guidelines by reference. A copy may be obtained from the American College of Occupational and Environmental Medicine, 25 Northwest Point Blvd., Suite 700, Elk Grove Village, Illinois, 60007-1030 (www.acoem.org).

The reference section at the end of Section 9792.20 has been amended to add Title 8, CCR sections 9789.10-9789.111 as reference. These sections encompassed the Official Medical Fee Schedule (OMFS) referenced in Section 9792.20(e).

Subdivision (e) has been amended to add a comma following the phrase "physical exam." Amended proposed Section 9792.20(e) now states:

> (e) "Functional improvement" means either a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management visit billed under the Official Medical Fee Schedule (OMFS) pursuant to Sections 9789.10-9789.111; and a reduction in the dependency on continued medical treatment.

The comma following the phrase "physical exam" in the definition of the term "functional improvement" clarifies that not only the reduction in work restrictions, but also the clinically significant improvement in activities of daily living, are measured during the history and physical exam and must be documented as part of the evaluation and management visit billed under the Official Medical Fee Schedule (OMFS).

Modifications to Section 9792.21 Medical Treatment Utilization Schedule

Subdivision 9792.21(a)(1) incorporating the ACOEM Practice Guidelines, 2nd Edition, into the schedule and setting forth the source and address where a copy of the guidelines may be obtained has been amended to reflect the correct source and address. Amended proposed Section 9792.21(a)(1) now states:

> The American College of Occupational and Environmental Medicine's Occupational Medicine Practice Guidelines (ACOEM Practice Guidelines), Second Edition (2004). A copy may be obtained from the American College of Occupational and Environmental Medicine, 25 Northwest Point Blvd., Suite 700, Elk Grove Village, Illinois, 60007-1030 (www.acoem.org).

Subdivision 9792.21(a)(2) sets forth the Acupuncture Medical Treatment Guidelines. **Subdivision 9792.21(a)(2)(C)** sets forth the frequency and duration of acupuncture or acupuncture with electrical stimulation may be performed. **Subdivision 9792.21(a)(2)(C)(iv)**, allowing for 14 treatments maximum, has been deleted from the regulations for clarification purposes.

It was determined that Section 9792.21(a)(2) was confusing as previously drafted. Section 9792.21(a)(2)(C)(iii) allowed for 3 to 6 acupuncture treatments, and Section 9792.21(a)(2)(C)(iv) allowed for 14 treatments, all subject to functional improvement pursuant to Section 9792.21(a)(2)(D). It was determined that Section 9792.21(a)(2)(C)(iv) allowing for 14 treatments maximum, was confusing because the treatment may be continued upon a showing of functional improvement after the initial series of treatments under Section 9792.21(a)(2)(C)(iii).

It was further determined that Section 9792.21(a)(2)(C)(iv) might be interpreted to constitute a cap on treatment, which was not the intention of the proposed regulations. The requirement that acupuncture achieve functional improvement serves to appropriately justify continued acupuncture treatment as this would lead to "a clinically significant improvement in activities of daily living or a reduction in work restrictions …, and a reduction in the dependency on continued medical treatment." Accordingly, Section 9792.21(a)(2)(C)(iv) was deleted from the regulations for clarification purposes.

Modifications to Section 9792.22 Presumption of Correctness, Burden of Proof and Strength of Evidence

Subdivision (c)(1)(A) setting forth Table A – Criteria Used to Rate Randomized Controlled Trials has been amended. Table A, under the "Randomization" criteria has been amended to include an explanation of the context in which the term successful is used. The explanation as amended now in the text of the proposed regulations states:

> "Simply allocating individuals to groups does not constitute sufficient grounds to assess the success of randomization. The groups must be comparable; otherwise, the randomization was unsuccessful".

During the 1st 15-day comment period, a comment was received from the public that an explanation of the context in which the term successful is used is necessary to clarify Section 9792.22(c)(1)(A). Successful randomization is a statistical concept. It entails, as stated in *Evidence-based Medicine: How to Practice and Teach EBM* (2005), at p. 118, "Randomization balances the treatment groups for prognostic factors, even if we don't yet know enough about the target disorder to know what they all are. If these factors exaggerated the apparent effects of an otherwise ineffectual treatment, the effects of their imbalance could lead to the false-positive conclusion that the treatment was useful when in fact it wasn't. In contrast, if they nullified or counteracted the effects of a really efficacious treatment, this could lead to a false-negative conclusion that a useful treatment was useless or even harmful. We should insist on random allocation to treatment because it comes closer than any other research design to creating groups of patients at the start of the trial who are identical in their risk of the event we are trying to prevent. We determine if the investigators used some method analogous to tossing a coin to assign patients to treatment groups."

After discussions with ACOEM, ACOEM has agreed that it is necessary for clarification purposes to add an explanation of the context in which the term successful is used in Table A. It is correct that simply allocating individuals to groups does not constitute sufficient grounds to assess the success of randomization. In order to assess the success of randomization, the additional factor is that the groups must be comparable, otherwise the randomization was unsuccessful. Unsuccessful randomization can also be addressed by statistically controlling for variables known to be associated with the outcome measure under investigation in any analysis. Pursuant to a document submitted by ACOEM entitled *Amendments to ACOEM's Methodology Advances for Occupational Practice Guidelines, 2nd Edition,* dated March 13, 2007, which has been added to the rulemaking file, Subdivision (c)(1)(A) setting forth Table A – Criteria Used to Rate Randomized Controlled Trials has been amended as indicated above.

Subdivision (c)(1)(A) setting forth Table A – Criteria Used to Rate Randomized Controlled Trials has further been amended. Table A, under the Co-Interventions Criteria has been amended. The criterion now reflects how co-interventions were controlled for rather than avoided. The section now states:

> **Controlled for Co-interventions:** The degree to which the study design controlled for multiple interventions (e.g., a combination of stretching exercises

and anti-inflammatory medication or mention of not using other treatments during the study).

The change reflecting how co-interventions were controlled for rather than avoided was based on a public comment requesting that this criterion be changed to reflect how any co-interventions were controlled rather than how they were avoided. The commenter stated that while co-interventions can mask significant effects or make non-significant effects appear significant, they can be controlled much more practically than they can be avoided.

In reviewing the comment, DWC notes that co-interventions are problematic, especially in musculoskeletal studies where they are common. Yet, the strength of the ACOEM methodology is that it recognizes the problem and does not exclude articles with such co-interventions, but rather incorporates this issue into the article rating. It is not possible to control for co-interventions in all circumstances, and in many studies they are tracked poorly such that an independent analysis of this problem is not possible. However, because there may be flaws, ACOEM has agreed that it is better to include a rating criterion that accounts for co-intervention, rather than excluding studies that did not control for them. ACOEM has amended this portion of Table A to reflect that the criterion should reflect how co-interventions were controlled for rather than avoided. (See, *Amendments to ACOEM's Methodology Advances for Occupational Practice Guidelines, 2nd Edition*, March 13, 2007, which has been added to the rulemaking file.)

For the benefit of the public, the entire amended Table A—Criteria Used to Rate Randomized Controlled Trials is set forth below, and the amended areas are highlighted in italics:

§ 9792.22(c)(1)(A Table A—Criteria Used to Rate Randomized Controlled Trials

Studies shall be rated using the following 11 criteria. Each criterion shall be rated 0, 0.5, or 1.0, thus the overall ratings range from 0-11. A study is considered low quality if the composite rating was 3.5 or less, intermediate quality if rated 4-7.5, and high quality if rated 8-11.

Criteria	Rating Explanation
Randomization: Assessment of the degree that randomization was both reported to have been performed and successfully* achieved through analyses of comparisons of variables between the two groups. **Simply allocating individuals to groups does not constitute sufficient grounds to assess the success of randomization. The groups must be comparable; otherwise, the randomization was unsuccessful.*	Rating is "0" if the study is not randomized or reports that it was and subsequent analyses of the data/tables suggest it either was not randomized or was unsuccessful. Rating is "0.5" if there is mention of randomization and it appears as if it was performed, however there are no data on the success of randomization, it appears incomplete, or other questions about randomization cannot be adequately addressed. Rating is "1.0" if randomization is specifically stated and data reported on subgroups suggests that the study did achieve successful randomization.

Treatment Allocation Concealed: Concealment of the allocation scheme from all involved, not just the patient.	Rating is "0" if there is no description of how members of the research team or subjects would have not been able to know how they were going to receive a particular treatment, or the process used would not be concealed. Rating is "0.5" if the article mentions how allocation was concealed, but the concealment was either partial involving only some of those involved or other questions about it are unable to be completely addressed. Rating is "1.0" if there is a concealment process described that would conceal the treatment allocation to all those involved.
Baseline Comparability: Measures how well the baseline groups are comparable (e.g., age, gender, prior treatment).	Rating is "0" if analyses show that the groups were dissimilar at baseline or it cannot be assessed. Rating is "0.5" if there is general comparability, though one variable may not be comparable. Rating is "1.0" if there is good comparability for all variables between the groups at baseline.
Patient Blinded	Rating is "0" if there is no mention of blinding of the patient. Rating is "0.5" if it mentions blinding, but the methods are unclear. Rating is "1.0" if the study reports blinding, describes how that was carried out, and would plausibly blind the patient.
Provider Blinded	Rating is "0" if there is no mention of blinding of the provider. Rating is "0.5" if it mentions blinding, but the methods are unclear. Rating is "1.0" if the study reports blinding, describes how that was carried out and would plausibly blind the provider.
Assessor Blinded	Rating is "0" if there is no mention of blinding of the assessor. Rating is "0.5" if it mentions blinding, but the methods are unclear. Rating is "1.0" if the study reports blinding, describes how that was carried out and would plausibly blind the assessor.

Controlled for Co-interventions: *The degree to which the study design controlled for multiple interventions (e.g., a combination of stretching exercises and anti-inflammatory medication or mention of not using other treatments during the study).*	Rating is "0" if there are multiple interventions or no description of how this was avoided. Rating is "0.5" if there is brief mention of this potential problem. Rating is "1.0" if there is a detailed description of how co-interventions were avoided.
Compliance Acceptable: Measures the degree of non-compliance.	Rating is "0" if there is no mention of non-compliance. Rating is "0.5" if non-compliance is briefly addressed and the description suggests that there was compliance, but a complete assessment is not possible. Rating is "1.0" if there are specific data and the non-compliance rate is less than 20%.
Dropout Rate: Measures the drop-out rate.	Rating is "0" if there is no mention of drop-outs or it cannot be inferred from the data presented. Rating is "0.5" if the drop-out issue is briefly addressed and the description suggests that there were few drop-outs, but a complete assessment is not possible. Rating is "1.0" if there are specific data and the drop-out rate is under 20%.
Timing of Assessments: Timing rates the timeframe for the assessments between the study groups.	Rating is "0" if the timing of the evaluations is different between the groups. Rating is "0.5" if the timing is nearly identical (e.g., one day apart). Rating is "1.0" if the timing of the assessments between the groups is identical.
Analyzed by Intention to Treat: This rating is for whether the study was analyzed with an intent to treat analysis.	Rating is "0" if it was not analyzed by intent to treat. Rating is "0.5" if there is not mention of intent to treat analysis, but the results would not have been different (e.g., there was nearly 100% compliance and no drop-outs). Rating is "1.0" if the study specifies analyses by intention

	to treat.
Lack of Bias: This rating does not enter into the overall rating of an article. This is an overall indication of the degree to which biases are felt to be present in the study.	Rating is "0" if there are felt to be significant biases that are uncontrolled in the study and may have influenced the study's results. Rating is "0.5" if there are felt to be some biases present, but the results are less likely to have been influenced by those biases. Rating is "1.0" if there are few biases, or those are well controlled and unlikely to have influenced the study's results.

Modifications to Section 9792.23 Medical Evidence Evaluation Advisory Committee

Section 9792.23

Subdivision (a)(2) has been amended to include members of the specialty boards who are approved by the Medical Board of California (MBC) in the Medical Evidence Evaluation Advisory Committee. Subdivision (a)(2) now states:

> The members of the medical evidence evaluation advisory committee shall be appointed by the Medical Director, or his or her designee, and shall consist of 17 members of the medical community, holding a Medical Doctor (M.D.), Doctor of Osteopathy (D.O.), who are board certified by an American Board of Medical Specialties (ABMS) or American Osteopathic Association approved specialty boards (AOA) respectively, Medical Doctors (M.D.), who are board certified by a Medical Board of California (MBC) approved specialty board, Doctor of Chiropractic (D.C.), Physical Therapy (P.T.), Occupational Therapy (O.T.), Acupuncture (L.Ac.), Psychology (PhD.), or Doctor of Podiatric Medicine (DPM) licenses, and representing the following specialty fields:

This section was amended based on a public comment stating that Section 9792.23(a)(2) limits M.D. members of that committee to those who are board certified by an American Board of Medical Specialties (ABMS). The commenter indicated that the Medical Board of California (MBC) established a process to review and approve certification training programs that can demonstrate "equivalence" to ABMS certification programs, and that to date, the MBC has approved four specialty certification programs as equivalent to ABMS. These boards include: American Board of Facial Plastic and Reconstructive Surgery; American Board of Pain Medicine; American Board of Sleep Medicine; and The American Board of Spine Surgery. Based on this comment it was agreed that the Medical Board of California (MBC) has approved a number of specialty boards which are not part of the American Board of Medical Specialties (ABMS). Proposed Section 9792.23(a)(2) was be amended to include members of the specialty boards who are approved by the Medical Board of California (MBC).

Subdivision (c) has been amended clarify to the process to be used by the medical evidence evaluation advisory committee in making recommendations to the Medical Director to revise, update or supplement the medical treatment utilization schedule. Proposed Section 9792.23(c) now states:

> To evaluate evidence when making recommendations to revise, update or supplement the medical treatment utilization schedule, the members of the medical evidence evaluation advisory committee shall:
>
> (1) Apply the requirements of subdivision (b) of Section 9792.22 in reviewing medical treatment guidelines to insure that the guidelines are scientifically and evidence-based, and nationally recognized by the medical community;
>
> (2) Apply the ACOEM's strength of evidence rating methodology to the scientific evidence as set forth in subdivision (c) of Section 9792.21 after identifying areas in the guidelines which do not meet the requirements set forth in subdivision (b) of Section 9792.21;
>
> (3) Apply in reviewing the scientific evidence, the ACOEM's strength of evidence rating methodology for treatments where there are no medical treatment guidelines or where a guideline is developed by the Administrative Director, as set forth in subdivision (c) of Section 9792.21.

The proposed amendment to Subdivision (c) resulted from general comments from the public wherein it became apparent that the proposed regulations were not clear as to the process to be used by the medical evidence evaluation advisory committee in making recommendations to the Medical Director to revise, update or supplement the medical treatment utilization schedule. The regulations now clarify that the committee first will apply the requirements of subdivision (b) of Section 9792.22 in reviewing medical treatment guidelines to insure that the guidelines are scientifically and evidence-based, and nationally recognized by the medical community, and then apply the ACOEM's strength of evidence rating methodology to the scientific evidence as set forth in subdivision (c) of Section 9792.21 after identifying areas in the guidelines which do not meet the requirements set forth in subdivision (b) of Section 9792.21. The committee is also responsible to apply in reviewing the scientific evidence, the ACOEM's strength of evidence rating methodology for treatments where there are no medical treatment guidelines or where a guideline is developed.

Amended Economic and Fiscal Impact Statement Added to the Rulemaking File

An Amended Economic and Fiscal Impact Statement (Form 399) has been added to the rulemaking file reflecting the changes to the cost impact analysis resulting from the proposed modifications to the text of the regulations relating to the Acupuncture Medical Treatment Guidelines, Proposed Section 9792.21(a)(2).